Medical Devices Safety Notice

The National Health Regulatory Authority would like to alert all governmental and private healthcare facilities, local agents and distributors that the below medical device:

Device Details	
Device Name	QUADROX-iD Pediatric with BIOLINE Coating
Device Model	BE-HMOD 30000
Lot No.	70124702, 70120467, 70121343, 70122531, 70125287, 70130805, 70124701, 70119853, 70123312, 70122267, 70123904, 70121443, 70119850, 70121443, 70119850 and 70123493
Manufacturer	MAQUET Cardiopulmonary GmbH
Country of Origin	Germany
Reference	https://www.sfda.gov.sa/ar/medicaldevices/Weekly%20Alerts/(SG-1911-148-H).pdf
Device picture	
Reason of Recall	NHRA initiates this FSN due to that the sterile barrier system of the QUADROX-iD Pediatric oxygenator may be compromised during transportation Under unfavorable transport conditions excessive movement of the device and its accessories in the carton

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	can lead to stress points that could compromise the sterile barrier of the packaging pouches.
Action should be taken	Incase of having the above defected lot numbers in your stock, please contact your authorized representative to take the necessary action for replacement.

Your cooperation is highly appreciated in improving health services in the Kingdom of Bahrain.

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